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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,530	01/29/2004	Henrich Cheng	681942-1US	2231
570	7590	05/14/2007	EXAMINER	
AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103			MENDOZA, MICHAEL G	
			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			05/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/766,530	CHENG, HENRICH
	<b>Examiner</b>	<b>Art Unit</b>
	Michael G. Mendoza	3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-21,23-28 and 30-32 is/are rejected.
- 7) Claim(s) 22,29 and 33 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 August 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                         |

## DETAILED ACTION

### *Drawings*

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are dark and unclear. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.
2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 30-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Human beings and/or human anatomy are not statutory subject matter and as such cannot be positively set forth as an element(s) of a claimed invention.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-21 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. 6235041.

7. As to claims 1-9, 12-19, and 23-26, Cheng et al. teaches a method of functionally connecting a portion of the peripheral nervous system of a vertebrate to a portion of the central or peripheral nervous system

of the vertebrate, comprising the steps of bringing portion of the peripheral nervous system and the portion of the central or peripheral nervous system close to each other, applying to the gap between the two portions a fibrin glue mixture comprising a growth factor, fibrinogen, aprotinin and divalent calcium ions so that the fibrin glue mixture (col. 6, lines 1-16) is simultaneously in contact with the two portions, and forming an attachment between the portion of the peripheral nervous system and the portion of the central or peripheral nervous system of the vertebrate (col. 1, lines 27-34); wherein the growth factor is selected from the group

consisting of a glial cell line-derived neurotrophic factor, transforming growth factor-beta, fibroblast growth factor, platelet-derived growth factor, and epidermal growth factor, vascular endothelial growth factor, and neurotrophin (col. 5, lines 66-67); wherein the fibroblast growth factor is acidic fibroblast growth factor; wherein the divalent calcium ions are provided by the addition of calcium chloride or calcium carbonate; wherein the fibrin glue mixture is acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, line 1-16); the step of introducing a tissue graft to the gap between the portion of the peripheral nervous system and the portion of the central nervous system; wherein tissue graft is a sural or intercostal nerve of said vertebrate (col. 7, lines 55-60).

8. As to claims 10, 11, 20, and 21, it has been held to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.C. 408. (1961).

9. As to claim 27, Cheng et al. teach a mixture comprising acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, lines 1-16).

10. As to claim 28, Cheng et al. teaches a vial B with 1 ml of aprotinin solution with 1000 KIU bovine lung aprotinin. This solution is mixed with vial D containing 2.5 ml of calcium chloride solution. Bringing the total volume of the solution of B + D to 3.5 ml. Added to the solution of C + D, dry fibrinogen between 115-232 mg in a vial A and dry thrombin between 4.9-11.1 mg in a vial C, to bring the total volume above 3.5 ml. For ease of calculation the examiner will use the solution volume of 3.5 ml. The solution of

3.5 ml with a total of 1000 KIU of aprotinin in the solution would equate to approximately 286 KIU/ml of solution. Therefor Cheng et al. reads on the limitation of the fibrin glue mixture comprises 0.0001-1000 mg/ml of fibroblast growth factor, 10-1000 mg/ml of fibrinogen, 10-500 KIU/ml of aprotinin and 1-100 mM of calcium chloride

***Allowable Subject Matter***

11. Claims 22, 29, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MM



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER